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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of  
VUNJAK-NOVAKOVIC, Gordana et al.

Serial No.: 10/815,778

Filed: April 2, 2004

For: CARTILAGE IMPLANT  
ASSEMBLY AND METHOD FOR  
IMPLANTATION

X

Group Art Unit: 1657

Examiner: Satyendra K. SINGH

Confirmation No.: 8172

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. §§1.97 and 1.98, applicants and their attorney respectfully request that the following documents be made of record in the official United States Patent and Trademark Office file relating to the above-identified application. The citation of these documents should not be construed as an admission that they constitute statutory prior art with respect to the present invention. In accordance with 37 C.F.R. §1.98(a)(2)(ii), copies of the following U.S. patents and publications are not submitted herewith.

**U.S. Patent Nos.**

5,329,846	6,165,487	6,630,000
5,336,616	6,261,586	6,761,739
5,545,222	6,267,786	6,855,167
5,662,710	6,270,528	6,890,354
5,888,219	6,361,565	6,933,328
5,899,939	6,458,144	7,044,968
6,025,538	6,503,277	7,358,284
6,132,472	6,591,581	7,488,348

**U.S. Patent Application Publication Nos.**

2001/0018619 A1  
2001/0021875 A1  
2007/0299517 A1  
2007/0179607 A1  
2008/0065210 A1  
2008/0039954 A1  
2008/0125863 A1  
2008/0305145 A1  
2009/0043389 A1  
2009/0069901 A1  
2009/0076624 A1

**Foreign Patent Application Publication Nos.**

EP 0739631 A2  
EP 1719531 A2\*  
WO 03/007805 A2\*  
WO 03/007805 A3\*  
WO 03/007879 A3\*  
WO 2004/096983 A3\*  
WO 2005/110278 A3\*  
WO 2006/042311 A3\*

**Foreign Patent Nos.**

EP 0762903 B1\*  
EP 1237511 B1\*  
EP 0739631 B1

**Non-Patent Documents**

Hoffman, "Hydrogels for Biomedical Applications", Advanced Drug Delivery Reviews, 2002, Vol. 43, pp. 3-12.
Dahlberg et al., "Demineralized Allogeneic Bone Matrix for Cartilage Repair", Journal of Orthopaedic Research, 1991, Vol. 9, pp. 11-19.
Lu et al., "Minced Cartilage without Cell Culture Serves as an Effective Intraoperative Cell Source for Cartilage Repair", Journal of Orthopaedic Research, June 2006, Vol. 24, pp 1261-1270.

Stone et al., "Articular Cartilage Paste Grafting to Full-Thickness Articular Cartilage Knee Joint Lesions: A 2- to 12-Year Follow-up", <i>Arthroscopy: The Journal of Arthroscopic and Related Surgery</i> , March 2006, Vol. 22, No. 3, pp 291-299.
Newman, "Articular Cartilage Repair", <i>American Journal of Sports Medicine</i> , 1998, Vol. 26, No. 2, pp 309-324.
Brittberg et al., "Treatment of Deep Cartilage Defects in the Knee with Autologous Chondrocyte Transplantation", <i>New England Journal of Medicine</i> , October 6, 1994, Vol. 331, No. 14, pp. 889-895.
Nixon et al., "Enhanced Repair of Extensive Articular Defects by Insulin-like Growth Factor-I-Laden Fibrin Composites", <i>Journal of Orthopaedic Research</i> , 1999; 17:475-487.
International Cartilage Repair Society, "Cartilage Injury Evaluation Package", <a href="http://www.cartilage.org">www.cartilage.org</a> , 2000.
Richardson et al., "Repair of Human Articular Cartilage After Implantation of Autologous Chondrocytes", <i>Journal of Bone and Joint Surgery [Br]</i> , 1999; 81-B:1064-1068.
Brittberg et al., "Autologous Chondrocytes Used for Articular Cartilage Repair: An Update", <i>Clinical Orthopaedics and Related Research</i> , 2001; No. 391 Suppl: S337-S348.
Peterson et al., "Two- to 9-year Outcome After Autologous Chondrocyte Transplantation of the Knee", <i>Clinical Orthopaedics and Related Research</i> , 2000; No. 374: 212-234.
Peterson et al., "Autologous Chondrocyte Transplantation: Biomechanics and Long-term Durability", <i>American Journal of Sports Medicine</i> , 2002, Vol. 30, No. 1, pp. 2-12.
Messner et al., "Cartilage Repair: A Critical Review", <i>Acta Orthopaedica Scandinavica</i> , 1996, Vol. 67, No. 5, pp. 523-529
Messner et al., "The Long-term Prognosis for Severe Damage to Weight-bearing Cartilage in the Knee: A 14-year Clinical and Radiographic Follow-up in 28 Young Athletes", <i>Acta Orthopaedica Scandinavica</i> , 1996, Vol. 67, No. 2, pp. 165-168.

Buckwalter et al., "Articular Cartilage: Degeneration and Osteoarthritis, Repair, Regeneration, and Transplantation", AAOS Instructional Course Lectures, 1998; 47:487-504.
Breinan et al., "Effect of Cultured Autologous Chondrocytes on Repair of Chondral Defects in a Canine Model", Journal of Bone and Joint Surgery [Am], October 1997; Vol. 79-A, No. 10, 1439- 1451.
Breinan et al., "Autologous Chondrocyte Implantation in a Canine Model: Change in Composition of Reparative Tissue with Time", Journal of Orthopaedic Research, 2001; 19:482-492.
Brittberg et al., "Rabbit Articular Cartilage Defects Treated with Autologous Cultured Chondrocytes", Clinical Orthopaedics and Related Research, 1996; 326:270-283.
Nehrer et al., "Chondrocyte-seeded Collagen Matrices Implanted in a Chondral Defect in a Canine Model", Biomaterials, 1998; 19:2313-2328.
Vunjak-Novakovic et al., "Bioreactor Cultivation Conditions Modulate the Composition and Mechanical Properties of Tissue-Engineered Cartilage", Journal of Orthopaedic Research, 1999; 17:130-138.
Bursac, "Collagen Network Contributions to Structure-Function Relationships in Cartilaginous Tissues in Compression" (Dissertation), Boston University College of Engineering, 2002.
Gooch et al., "IGF-I and Mechanical Environment Interact to Modulate Engineered Cartilage Development", Biochemical and Biophysical Research Communications, 2001; 286:909-915.
Pei et al., "Growth Factors for Sequential Cellular De- and Re-differentiation in Tissue Engineering", Biochemical and Biophysical Research Communications, 2002; 294:149-154.
Obradovic et al., "Integration of Engineered Cartilage", Journal of Orthopaedic Research, 19:1089-1097, 2001.
Schaefer et al., "Tissue Engineered Composites for the Repair of Large Osteochondral Defects", Arthritis & Rheumatism, 46(9): 2524-2534 (2002).
Pei et al., "Bioreactors Mediate the Effectiveness of Tissue Engineering Scaffolds", The FASEB Journal, 16:1691-1694, published online (August 7, 2002), 10.1096/fj.02-0083fje.

Madry et al., "Gene Transfer of a Human Insulin-like Growth Factor I cDNA Enhances Tissue Engineering of Cartilage", Human Gene Therapy, 13: 1621-1630 (September 1, 2002).
Pearson et al. (eds.), American Association of Tissue Banks, Standards for Tissue Banking, 2008 (12 <sup>th</sup> ed.), pp. 53-56, 86-88.
Osteo Sponge product information, Bacterin International Inc., May 2005.
Nolan et al., "Living Bone Grafts", BMJ, Volume 304, June 13, 1992, pp 1520 and 1521.
Stone et al., "One-Step American Technique of Articular Cartilage Paste Grafting to Traumatic and Arthritic Defects in the Knee Joint (2-7 Years Follow-Up)", downloaded from <a href="http://web.archive.org/web/20041205005845/http://www.stoneclinic.com/onestep.thm">http://web.archive.org/web/20041205005845/http://www.stoneclinic.com/onestep.thm</a> ; published December 5, 2004.

#### **CO-PENDING PATENT APPLICATIONS**

Applicants wish to inform the Examiner of the following co-pending patent applications, which are at least partially commonly owned with the present application:

1. U.S. Patent Application Serial No. 12/147,042 ("the '042 Application"), filed June 26, 2008, is a reissue application based on U.S. Patent No. 7,067,123, which was previously made of record in the present application. A copy of the '042 Application, as filed (including a Preliminary Amendment), is attached. All references cited in the '042 Application have either been previously cited in the present application or are cited herein. The title and applicants for the '042 Application are as follows:

Title: NOVEL GLUE FOR CARTILAGE REPAIR

Applicants: Katherine A. Gomes, Arthur A. Gertzman, Moon Hae Sunwoo and  
William W. Tomford

2. U.S. Patent Application Serial No. 12/191,490 ("the '490 Application"), filed August 14, 2008, is a divisional application of the present application. The '490 Application was published as U.S. Patent Application Publication No. 2009/0043389 A1, which is cited herein.

3. U.S. Patent Application Serial No. 12/179,034 ("the '034 Application"), filed July 24, 2008, is a continuation application of U.S. Patent Application Serial No. 10/438,883, which was previously made of record in the present application. The '034 Application was published as U.S. Patent Application Publication No. 2009/0069901 A1, which is cited herein.

4. U.S. Patent Application Serial No. 12/328,306 ("the '306 Application"), was filed December 4, 2008. A copy of the '306 Application, as filed, is attached. The title and applicants for the '306 Application are as follows:

Title: CANCELLOUS BONE IMPLANT FOR CARTILAGE REPAIR

Applicants: Eric J. Semler, Alex B. Callahan, Katherine G. Truncale and Roman Shikhanovich

5. International Patent Application No. PCT/US08/85522 ("the '85522 PCT Application"), filed December 4, 2008 is the international counterpart of the '306 Application. A copy of the '85522 PCT Application, as filed, is attached. The title and applicants for the '85522 PCT Application are as follows:

Title: CANCELLOUS BONE IMPLANT FOR CARTILAGE REPAIR

Applicants: Musculoskeletal Transplant Foundation, Eric J. Semler, Alex B. Callahan, Katherine G. Truncale and Roman Shikhanovich

6. U.S. Patent Application Serial No. 12/322,996 ("the '996 Application"), filed February 9, 2009, is a continuation-in-part of (i) U.S. Patent Application Serial No. 10/438,883 filed May 16, 2003, (ii) U.S. Patent Application Serial No. 11/151,270 filed June 14, 2005, and (iii) U.S. Patent Application Serial No. 12/179,034 filed July 24, 2008. A copy of the '996 Application, as filed, is attached. The title and applicants for the '996 Application are as follows:

Title: ALLOGRAFT OSTEOCHONDRAL PLUG COMBINED WITH  
CARTILAGE PARTICLE MIXTURE

Applicants: Katherine G. Truncale, Judith I. Yannariello-Brown, Arthur A. Gertzman, William W. Tomford, Moon Hae Sunwoo, Yen-Chen Huang

7. U.S. Patent Application Serial No. 12/381,072 ("the '072 Application"), filed March 5, 2009, is a continuation-in-part of (i) U.S. Patent Application Serial No. 11/657,042 filed January 24, 2007; (ii) U.S. Patent Application Serial No. 12/043,001 filed March 5, 2008; (iii) U.S. Patent Application Serial No. 12/328,306 filed December 4, 2008; and (iv) U.S. Patent Application Serial No. 12/079,629 filed March 26, 2008, which is a divisional of U.S. Patent Application Serial No. 10/960,960 filed October 12, 2004, now abandoned. The title and applicants for the '072 Application are as follows:

Title: CANCELLOUS CONSTRUCTS, CARTILAGE PARTICLES AND COMBINATIONS OF CANCELLOUS CONSTRUCTS AND CARTILAGE PARTICLES

Applicants: Katherine G. Truncale, Eric J. Semler, Judith I. Yannariello-Brown, Arthur A. Gertzman, William W. Tomford, Moon Hae Sunwoo, Roman Shikhanovich, Alex B. Callahan, Morris L. Jacobs, John C. Munson, and Yen-Chen Huang

8. International Patent Application No. PCT/US2009/001459 ("the '001459 PCT Application"), filed March 5, 2009 is the international counterpart of the '072 Application. The title and applicants for the '001459 PCT Application are as follows:

Title: CANCELLOUS CONSTRUCTS, CARTILAGE PARTICLES AND COMBINATIONS OF CANCELLOUS CONSTRUCTS AND CARTILAGE PARTICLES

Applicants: Musculoskeletal Transplant Foundation, Katherine G. Truncale, Eric J. Semler, Judith I. Yannariello-Brown, Arthur A. Gertzman, William W. Tomford, Moon Hae Sunwoo, Roman Shikhanovich, Alex B. Callahan, Morris L. Jacobs, John C. Munson, and Yen-Chen Huang

Applicants and their attorney also enclose copies of the following USPTO Communications from patent applications which are at least partially commonly owned with the present application:



1. A non-final Office Action mailed on November 12, 2008 in connection with U.S. Patent Application Serial No.: 10/438,883.

2. A final Office Action mailed on September 19, 2008 in connection with U.S. Patent Application Serial No. 11/081,103.

Applicants' attorney has completed United States Patent and Trademark Office Forms PTO/SB/08A and PTO/SB/08B. The completed forms are attached hereto.

Applicants' attorney notes that one of the previously filed Supplemental Information Disclosure Statements contained incorrect information in connection with some of the cited references. More particularly, the above-listed patent references having an asterisk (\*) were previously cited but incorrect publication dates for those references were erroneously included in the United States Patent and Trademark Office Form PTO/SB/08A. In such circumstances, those references are being cited herein with the correct publication date information on the attached Form PTO/SB/08A. One of those references is not in the English language (i.e., European Patent No. EP 1237511 B1), but corresponds to International Publication No. WO 01/043667 A1 and U.S. Patent No. 6,858,042, both of which were previously cited in the present application, and were published in the English language. Comments concerning the relevance of European Patent No. EP 1237511 are therefore believed to be unnecessary under 37 C.F.R. §1.98.

Applicants' attorney also notes that a previously filed Supplemental Information Disclosure Statement contained incomplete publication information for one of the non-patent documents that was cited therein. More particularly, Stone et al., "One-Step American Technique of Articular Cartilage Paste Grafting to Traumatic and Arthritic Defects in the Knee Joint (2-7 Years Follow-Up)" was previously cited without a publication date. In such circumstances, the Stone et al. publication is being cited herein with its publication date information (i.e., publication date of December 5, 2004) on the attached Form PTO/SB/08B.

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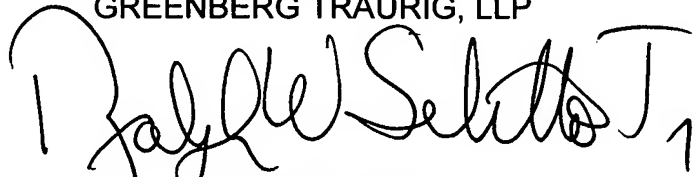
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Since this Supplemental Information Disclosure Statement is being submitted following the filing of a Request for Continued Examination on May 13, 2009, no fees are believed to be due in connection with the submission of same. However, if any such fees are due, including any Information Disclosure Statement submittal fees, the Examiner is hereby authorized to charge them to Deposit Account No. 501561.

Respectfully Submitted,

GREENBERG TRAURIG, LLP

A handwritten signature in black ink, appearing to read "Ralph W. Selitto, Jr.", written over the printed name.

By: Ralph W. Selitto, Jr.  
Reg. No. 26,996

GREENBERG TRAURIG, LLP  
200 Park Ave.  
P.O. Box 677  
Florham Park, NJ 07932  
(973) 443-3550 Direct  
(973) 295-1309 Fax  
selittor@gtlaw.com